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JANENE PEISKER
TEAM LEADER EXAMINATION
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AUSTRALIA

Patents Act 1990

Advanced Metal Coatings Pty Limited

PROVISIONAL SPECIFICATION

Invention Title:

Production of lesions in a body

The invention is described in the following statement:

Production of lesions in a body

Field of the Invention

This invention relates to the production of lesions in a human or animal body or the treatment of pain management. More particularly, the invention relates to a system for, and method of, producing lesions in a patient's body or in the treatment of pain management and to a component for use in the system.

Background to the Invention

Electromagnetic energy, in the form of radio frequency (RF) energy, is frequently used in human or animal bodies to produce lesions in the body for many applications such as, for example, cardiac ablation purposes, tumour ablation, etc as well as in the treatment of pain management. To apply the RF energy at the required site in the body, an electrode is used as a conductor with an electrode tip forming a first terminal of the circuit and the patient's body forming a ground electrode for the circuit so that, when the electrode tip is brought into contact with the site, a closed circuit is formed. A problem with this arrangement is that the impedance of the patient's body is high resulting in dissipation of the RF energy through the patient's body rather than being concentrated at the site.

For example, traditionally lesions have been produced in a patient's heart using a single active electrode system. The RF energy is applied to a small electrode tip towards the end of a catheter with an earth connection being made to the patient.

Summary of the Invention

According to a first aspect of the invention, there is provided a system for producing a lesion in a patient's body or in the treatment of pain management, the system including:

a generator for generating electromagnetic energy;

an energy division means connected to an output of the generator for dividing the energy generated by the generator; and

at least two active electrodes connected to outputs of the energy dividing means, each electrode receiving a part of the energy from the energy dividing means.

The energy applied by the electrodes to a site of the body may be out of phase.

According to a second aspect of the invention, there is provided a method of producing a lesion in a patient's body or of treating pain management, the method including the steps of:

generating electromagnetic energy;

diving the electromagnetic energy; and

feeding the divided energy to each of at least two active electrodes applied to a site of the patient's body.

The method may include feeding the energy to the active electrodes such that the energy provided to any one electrode is out of phase with the energy provided to any other electrode.

The energy generator may be in the form of an RF energy generator.

Preferably, the system uses at least two electrodes with the energy supplied to the electrodes being 180° out of phase with each other so that the total energy applied to the site in the patient's body is equivalent to the energy applied by a single electrode system.

It will be appreciated that both electrodes are, therefore, active electrodes in the sense that RF energy is supplied to each electrode.

Further, the system may use more than two electrodes with the electrodes then being arranged in groups on either side of the site so that energy is applied across the site to effect the production of the lesion.

The energy dividing means may be in the form of a transformer having a centre tap. The transformer may, conveniently, be an RF transformer capable of withstanding energy levels and frequencies used in the electrodes.

A secondary winding of the transformer may be tapped, preferably at its centre, with the tap being tied to ground through an indifferent electrode attached to the patient and a system ground of the RF generator. Each end of the secondary winding may then be connected to an electrode of the system.

The transformer may use a 1:1 ratio between the primary and secondary windings.

While the system has been designed specifically for the production of lesions in the heart for treatment of atrial fibrillation, the system may equally well be used for treatments of other forms of arrhythmia, for example, ventricular tachycardia. The method may therefore include arranging the electrode transmurally ie, through a ventricular wall of the heart for producing a transmural lesion at the relevant site to treat ventricular tachycardia.

To facilitate mounting of the electrodes at the relevant site, in particular, in treating ventricular tachycardia, the invention may further extend to a component for use with the system and method of the invention, as described above, the component comprising a pair of co-axially arranged electrodes.

In particular, at least one of the electrodes may be a screw-in or auger-tipped electrode which is screwed into the heart wall with the other electrode being in contact with the endocardium of the heart. It will be appreciated that the electrodes may be insulated from each other.

As a development of this arrangement, both electrodes may be screw-in or auger-tipped electrodes. In so doing, the depth of the tips of the electrodes can be optimised depending on the depth of the conductive fibres potentially causing the ventricular tachycardia.

Brief Description of the Drawings

The invention is now described by way of example with reference to the accompanying drawings in which:

Figure 1 shows a block diagram of a system, in accordance with the invention, for producing a lesion in a patient's body; and

Figure 2 shows a graph of various comparative waveforms.

Detailed Description of the Drawings

Referring initially to Figure 1 of the drawings, a system, in accordance with the invention, for producing a lesion in a patient's body is illustrated and is designated generally by the reference numeral 10. The system 10 comprises a generator 12 for generating electromagnetic energy, more particularly, radiofrequency (RF) energy.

An energy division means in the form of a transformer 14 is connected to an output of the RF generator 12. At least two electrodes 16 are connected to outputs of the transformer 14, as will be described in greater detail below.

The system 10 makes use of a patient's body as an impedance 18 to which an indifferent electrode 20 is connected. The indifferent electrode 20 is tied to a ground 22 of the RF generator 12.

The transformer 14 is a centre-tapped transformer. A secondary winding of the transformer 14 has a centre tap 24 to which the electrode 20 is connected. Other ends of each of the secondary windings of the secondary transformer formed by the centre tapping of the secondary winding have the electrodes 16 connected thereto.

The transformer 14 makes use of a 1:1 ratio between primary and secondary windings. Different ratios may be employed bearing in mind that if the windings of the secondary winding are increased, the voltage across each secondary winding will increase with a corresponding decrease in current.

In addition, the materials used in the transformer 14 are selected to be capable of withstanding energy levels and frequencies involved in ablative therapies. The transformer 14 and the materials used are optimised to ensure maximum transfer of energy to the active electrodes 16.

The system 10 is designed particularly for use in the production of lesions in a patient's body for treating various disorders such as atrial fibrillation, ventricular tachycardia, tumour ablation, pain management, etc. Traditionally, systems for treatment of these disorders have used a single electrode with the patient's body forming an earth connection. This results in a large percentage of energy dissipation through the patient's body rather than being used for ablative purposes at a site in the patient's body.

With the provision of two active electrodes 16 in the system 10 of the present invention, an inter-electrode impedance, illustrated schematically at 26, is created between the active electrodes 16 resulting in greater energy transfer between the electrodes 16 rather than through the patient's body.

A representation of this is shown in Figure 2 of the drawings where waveform 28 is the voltage waveform of a single electrode of a prior art system. Voltage waveforms 30 and 32 are the 180° out of phase waveforms of each active electrode 16 of the system 10 of the present invention and waveform 34 is the sum of the waveforms 30 and 32. Thus, it will be noted that the voltage between the electrodes 16, as represented by the waveform 34, is the same as the voltage of a single electrode 28 but that the energy is concentrated between the active electrodes 16 rather than between an electrode and any indifferent electrode relying on the patient's body.

It is to be noted that, in total, the energy of the system 10 is no higher than that of a prior art system as the energy applied to each active electrode 16 by the transformer 14 is half that applied to the single electrode of the prior art system.

The applicant believes that, with the concentration of energy between the active electrodes 16 of the present system 10, larger and deeper lesions may be formed between the two electrodes 16 than can be produced by a single electrode using the same RF energy. The reason for this is that the inter-

electrode impedance 26 is much lower than that of the patient's body resulting in energy transfer between the electrodes 16 rather than dissipation of energy through the patient's body.

Table 1 below shows various tests which have been carried out experimentally.

No.	Notes	Spacing (mm)	Power (W)	Time (s)	Depth (mm)
1	2cath 2mm elect in phase	0	20	120	4
2	2cath 2mm elect out phase	0	20	120	3.5
3	2cath 2mm elect out phase	2	20	120	3.5
4	2cath 2mm elect out phase	5	20	120	6
5	2cath 2mm elect out phase	6.5	20	120	4.5
6	2cath 2mm elect out phase	9	20	120	5
7	2cath 2mm elect in phase (crossed)	0	20	120	-
8	2cath 2mm elect in phase (crossed)	0	20	120	-
9	2cath 2mm elect in phase	0	20	120	4
10	1cath 2mm	-	20	120	4.5
11	Three burn series (as 10) #1	-	20	120	5
12	Three burn series (as 10) #2	-	20	120	5
13	Three burn series (as 10) #3	-	20	120	5
14	2cath 2mm elect in phase	7	20	120	3.5
15	2cath pairs elect out phase (long elect)	4	20	120	6
16	2cath 4mm elect in phase	0	20	120	0.5
17	2cath 4mm elect out phase	0	20	120	6
18	2cath 4mm elect out phase	4	20	120	6
19	2cath 4mm elect out phase	7	20	120	8
20	2cath 4mm elect out phase	11	20	120	8
21	2cath 4mm elect in phase	0	20	120	0.5
22	2cath 4mm elect in phase	6	20	120	0.5
23	1 cath 4mm	-	20	120	5
24	2cath 4mm elect out phase transmural	-	20	120	13 high damage
25	2cath 4mm elect out phase	4	10	120	5
26	2cath 4mm elect out phase	4	20	60	7
27	2cath 4mm elect out phase	4	20	30	5
28	2cath 4mm elect in phase transmural	-	20	120	6 low damage

Table 1

A comparison between the various tests carried out shows that, with the provision of two electrodes relying on complementary and 180° out of phase energy, deeper lesions are formed. Reference is made particularly to tests 19

and 23 where it is to be noted that, with the use of the two active electrodes 16, a deeper lesion was formed than was the case with a single electrode.

Once again, comparing items 24 and 28, relating to transmural lesions, the use of the two out of phase electrodes 16 of the present system 16 (test 24) resulted in a significantly deeper lesion than using two electrodes in phase as shown by test 28.

To create a transmural lesion, particularly for the treatment of atrial fibrillation, one electrode may be placed thorascopically through the chest with a second electrode being inserted via a catheter inside the heart to achieve lesions through the heart wall.

Another approach contemplated for use with the present system 10 is the use of two, co-axially arranged electrodes 16. At least one, preferably the outer, electrode 16 is a retractable electrode inserted via a catheter and screwed into position by means of a screw driver stylet inserted through a lumen of the catheter to extend the screw tipped electrode into the heart wall. The second electrode, which may be fixed or retractable, is placed in contact with the endocardium of the heart to effect the production of a transmural lesion.

The actual length of exposed metal of the screw electrode can be optimised by insulating a portion of the screw. For example, the screw tip may be 20mm long but only the most distal 5mm is exposed metal. It will also be appreciated that the actual depth to which the electrode is screwed into the heart wall is variable depending on the treatment required.

It will be appreciated that the two electrodes are insulated from each other.

A variation of this arrangement is the use of two screw-tipped electrodes insulated from each other.

The screw tip of one of the electrodes, preferably the outer electrode, has a larger pitch than the other, inner electrode so that, when the electrodes are extended out of the catheter, the one having the larger pitch is screwed into the heart wall to a greater depth. The finer pitched, inner electrode is urged into contact with the endocardium. Once again, screw depth can be optimised depending on the depth of the conductive fibres causing the arrhythmia.

The applicant is of the view that the use of concentric electrodes, in particular, would be useful for the treatment of ventricular tachycardia but could be of use in other applications as well.

Optimisation of the system 10 involves the positioning of the tap 24 on the secondary winding of the transformer 14 as well as the shape and size of the electrodes 16. To reduce charring at the site, the electrodes connected to each end of the secondary winding may be arranged in groups, for example, pairs. By placing the electrodes in groups, each electrode may impart lower energy to the site thereby reducing the likelihood of charring. In addition, use of multiple electrodes can be used for pain management with the RF energy being delivered through at least two of the electrodes simultaneously. The positioning of two electrodes may be less dangerous than a single electrode with an earth electrode. For example, in pain management where energy is applied to a patient's spine, placing an electrode on each side of the spine rather than one directly into the spine may be less risky.

In addition, for ablating a tumour, by placing the electrodes 16 on opposite sides of the tumour, more mass of the tumour can be ablated than with the use of a single electrode.

Accordingly, it is an advantage of the invention that a system 10, and method, are provided, where due to energy transfer between active electrodes 16 deeper lesion production and more accurate lesion production is facilitated. In addition, the use of a pair of active electrodes reduces the risks involved in the production of lesions for treatment of various disorders.

Further, the use of two, active electrodes is of significant benefit in creating linear lesion such as used in "Maze-like" procedures as well as transmural lesions which are beneficial in treating ventricular tachycardia.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this twenty-ninth day of October 2002

Advanced Metal Coatings Pty Limited
Patent Attorneys for the Applicant:

F B RICE & CO

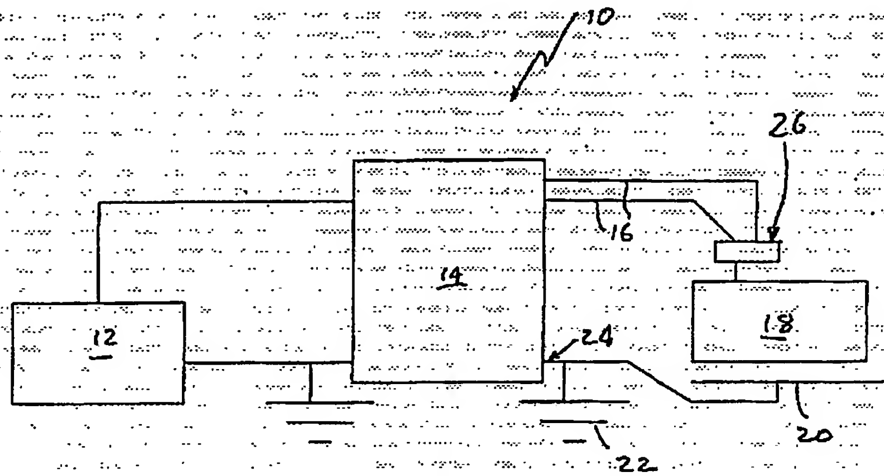
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FIG. 1

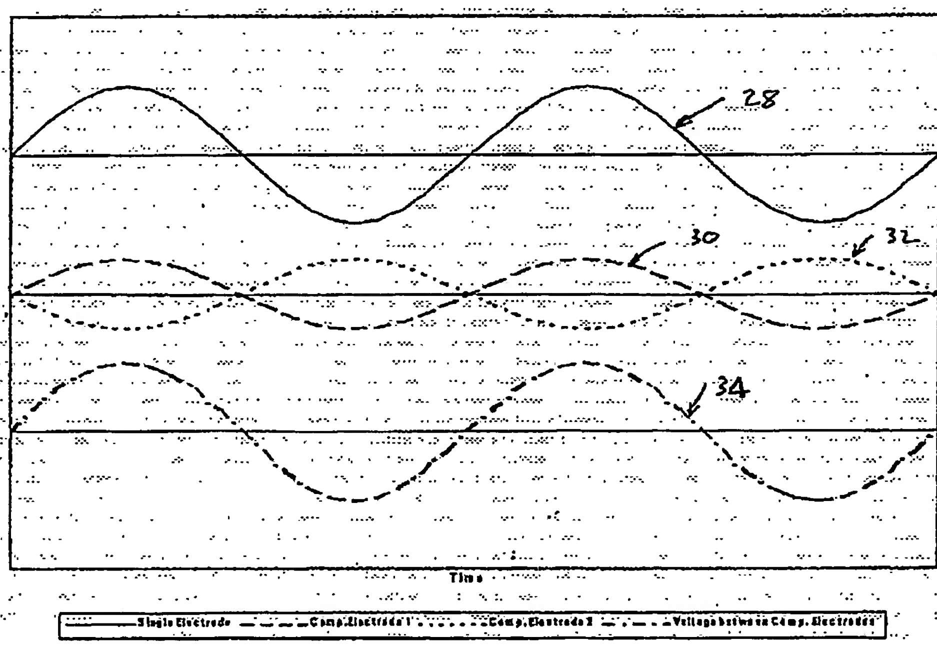
28
30
32
34
Time
Single Electrode
Comp. Electrode 1
Comp. Electrode 2
Voltage between Comp. Electrodes

FIG. 2